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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,629	01/11/2000	HARALD SEULBERGER	48141	5335

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WASHINGTON, DC 20005

EXAMINER
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KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding..

**Office Action Summary**

Application No.

09/462,629

Applicant(s)

SEULBERGER ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

5.0.0.0

### **STATUS OF THE APPLICATION**

1. This Office action is in response to the Amendment and Remarks filed on 9 March 2005.
2. Those objections or rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

4. In response to Applicant's request concerning a "legible" copy of the reference cited on the IDS of 29 October 2002, the file does not contain any copy of the reference (page 2 of the Remarks). In view of Applicant's remarks, it appears that said reference is redundant.

### ***Sequence Compliance of the Application***

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825.

The amino acid sequences on pages 24-26 do not comply with the sequence rules, because they do not have a sequence identifier in the specification nor are they in the sequence listing, with the exception of "HPPD\_Hv". Applicant is required to correct this matter of form in the specification.

Failure to comply with these requirements will be considered non-responsive to this Office action.

***Claim Objections***

6. Claims 1, 2, 14 and 25 remain objected to for the reasons of record.

The limitation "sequence" after "DNA" should be deleted from the instant claims because "sequence" is information and not a composition of matter. A DNA sequence is not a composition of matter because a sequence is merely descriptive information about a molecule. See the Federal Register, Vol. 66, No. 4, January 5, 2001, page 1095, center column, comment No. 13.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. Claims 1-14 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 7 October 2004. Applicant's arguments filed 9 March 2005 have been fully considered but they are not persuasive.

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Applicants argue that the application claims an isolated DNA encoding for barley HPPD on the basis of the genomic DNA sequence of the *H vulgare* HPPD. Applicants argue that the present application claims only a DNA encoding for genus *Hordeum* on the basis of the genomic DNA sequence of the species *H vulgare* and that there is a

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significant difference between a claim covering an entire phylum, and a claim covering only a genus. Applicants argue that due to the high degree of identity, it is justifiable to claim a certain genus (in the taxonomic sense) on the basis of an isolated DNA from a single species, that the high degree of conservation between DNA sequences encoding for HPPDS within the family Poaceae (formerly Graminae) is exemplified by a comparison between the HPPD from *Hordeum vulgare* and *Oryza sativa* (see the enclosed [Ralf Michael Schmidt] Declaration, Figures 1 and 2). Applicant argue that the homology between the coding region of these DNAs is 84%, although these organisms do not belong to the same genus, accordingly, one would reasonably conclude that the degree of homology between genes encoding for HPPD from genus *Hordeum* must be at least above 95%, and likely even higher (page 4 of the Remarks).

These arguments are not found to be persuasive. There are at least 32 recognized species of *Hordeum*; for example *H arizonicum*, *H bogdanii*, *H brachyantherum*, *H brevisubulatum*, *H bulbosum*, *H capense*, *H chilense*, *H comosum*, *H cordobense*, *H depressum*; of which Applicant only describes an isolated DNA encoding HPPD from one species, *Hordeum vulgare*, having the amino acid sequence of SEQ ID NO: 2. Applicants do not describe a representative number of species of the claimed genus, nor does Applicants describe any structural feature of a *Hordeum* HPPD that describes the claimed genus. Applicants do not describe the *Oryza sativa* HPPD or it's level of sequence identity with the described *H vulgare* species in the specification, hence, at the time of the invention one of skill in the art could not have made such an

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assumption, or recognized that Applicant was in possession of the invention as broadly claimed.

8. Claims 1-14 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated DNA encoding the amino acid sequence of SEQ ID NO: 2 and methods of using it and plants transformed therewith, does not reasonably provide enablement for an isolated DNA encoding any barley HPPD. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 7 October 2004. Applicant's arguments filed 9 March 2005 have been fully considered but they are not persuasive.

In addition to the arguments under written description outlined above, Applicants argues that on the basis of techniques that are comprehensively disclosed in the specification of the present application (Examples 1 and 2) or additional established methods and techniques well known to a person having ordinary skill in the art at the time of the invention, the isolation of genes encoding for HPPDS from other members of the genus *Hordeum* by e.g. simple PCR cloning approaches or the screening of cDNA libraries using the disclosed DNA as a probe is a routine task for a skilled person (page 4, 4<sup>th</sup> paragraph of the Remarks).

These arguments are not found to be persuasive for the reasons of record. The claims encompass any variant of any isolated DNA encoding a *Hordeum* HPPD, and thus are much broader than what Applicants teach one of skill in the art how to make

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and use. The recitation of "a *Hordeum vulgare* DNA encoding for a HPPD" is broader than what Applicants teach one of skill in the art how to make and use without undue trial and error experimentation because it encompasses mutations and variants not taught by Applicants.

**Conclusion**

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. No claims are allowed.

11. Claims 1-14 remain rejected

12. Claim 25 remains objected to.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER



David H. Kruse, Ph.D.  
20 May 2005

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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